

**IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF PENNSYLVANIA**

MAUREEN PIEKANSKI

Plaintiff,

v.

ALEX M. AZAR II, in his official
capacity as Secretary of the United
States Department of Health and
Human Services,

Defendant.

No. 3:20-CV-00687

(Judge Mariani)

(Magistrate Judge Carlson)

(Electronically Filed)

DEFENDANT’S STATEMENT OF UNDISPUTED MATERIAL FACTS

I. INTRODUCTION

Pursuant to Federal Rule of Civil Procedure 56 and Middle District of Pennsylvania LR 56.1, Defendant Secretary of the Department of Health and Human Services (the “Secretary”) hereby submits the following Statement of Undisputed Material Facts in support of his Motion for Summary Judgment and in opposition to Plaintiff’s Motion for Summary Judgment.

II. OPPOSITION TO PLAINTIFF’S STATEMENT OF UNDISPUTED MATERIAL FACTS

1-2. Undisputed.

3. Plaintiff’s interpretation of articles concerning Tumor Treatment Field Therapy (“TTFT”) that were published in the Journal of the American Medical

Association in 2015 and 2017 is neither material to any issue to be resolved on summary judgment nor a “fact.” Furthermore, the validity of Plaintiff’s interpretation is not readily apparent given that Plaintiff failed to cite the specific pages within these articles that purportedly support her interpretation. In any event, the articles are part of a much larger body of medical literature and speak for themselves.

4. It is undisputed that, on November 7, 2018, ALJ Gulin found that Plaintiff was entitled to Medicare coverage for TTFT provided during September, October, and November 2017. The remainder of this paragraph contains argument and/or discusses inadmissible ALJ determinations. *See* Secretary’s Memorandum of Law in Support of his Cross-Motion for Summary Judgment and in Opposition to Plaintiff’s Motion for Summary Judgment at (“D. Br.”) at § V.D.

5-9. Undisputed.

10. Plaintiff selectively quotes from ALJ Gulin’s decision, which identified three issues to be decided:

1. Whether the Elec Stim Cancer Treatment (E0766) provided to the Beneficiary on the dates of service meet Medicare coverage criteria.
2. Whether the services provided are medically necessary under Section 1862(a)(1)(A) of the Social Security Act (“Act”) and covered under Medicare.

3. If the services are found to be excluded from coverage under Section 1862(a)(1)(A), then another issue to be determined is whether payment may nevertheless be made to appellant under the limitation on liability provisions of Section 1879 of the Act.

Administrative Record (“AR”) [Dkt. No. 33] at 3187.

11. Plaintiff selectively quotes from ALJ Gulin’s decision, which found, *inter alia*, that: “[T]here is sufficient evidence supporting the Elec Stim Cancer Treatment (E0766) provided on the dates of service meets Medicare coverage criteria.” AR at 3191. ALJ Gulin’s decision speaks for itself.

12. Plaintiff selectively quotes from ALJ Gulin’s decision, which identified three issues to be decided, and speaks for itself. *See supra* ¶ 10.

13. Plaintiff selectively quotes from ALJ Gulin’s decision, which found, *inter alia*, that: “[T]here is sufficient evidence supporting the Elec Stim Cancer Treatment (E0766) provided on the dates of service meets Medicare coverage criteria.” AR at 3191. ALJ Gulin’s decision speaks for itself.

14-18. Undisputed.

19. Plaintiff selectively quotes from ALJ Glaze’s decision, which identified the following issue to be decided: “The issue is whether payment may be made for the OptuneTM tumor treatment field therapy (E0766) provided to the Beneficiary from December 14, 2017 through February 14, 2018, and if not, who is liable for any non-covered charges.” AR at 2574.

20. Undisputed.

21. Plaintiff selectively quotes from ALJ Glaze's decision, which contains several findings and speaks for itself. AR at 2577-78.

22. It is undisputed that Judge Gulin's decision was provided to Judge Glaze. The decisions, however, addressed different issues. *See* D. Br. at § V.B.

23. Undisputed.

24-49. Because these paragraphs rely on inadmissible evidence, they should be stricken or otherwise disregarded. *See* D. Br. at § V.D. In the event this evidence is admitted, the Secretary reserves his right to dispute these paragraphs.

50-51. Undisputed.

52. It is undisputed that ALJ Gulin characterized Plaintiff's GBM as newly-diagnosed in his November 7, 2018 decision concerning her claims from September – November 2017. AR at 3190. It is also undisputed that ALJ Glaze characterized Plaintiff's GBM as recurrent in his January 18, 2019 decision concerning her claims from December 2017 – February 2018. AR at 2577-78. The remainder of this paragraph concerns inadmissible evidence and should be stricken or otherwise disregarded. *See* D. Br. at § V.D. In the event this evidence is admitted, the Secretary reserves his right to dispute these paragraphs.

III. DEFENDANT'S STATEMENT OF UNDISPUTED MATERIAL FACTS

1. In April 2011, the United States Food and Drug Administration approved the marketing of the NovoTTF-100A device (later rebranded Optune)

manufactured and supplied to beneficiaries by Novocure, for the treatment of recurrent GBM. AR at 2506.

2. Following an open meeting and solicitation of public comments, in August 2014, the Medicare Administrative Contractors for Durable Medical Equipment (“DME MACs”) issued the original LCD for TTFT (the “2014 LCD”). AR at 2506. “The DME MACs determined that, based on the strength and quality of the evidence available at that time, TTFT was not reasonable and necessary for the treatment of GBM.” *Id.*

3. The 2014 LCD was in effect at the relevant time, *i.e.*, during the dates of service for the claims on appeal, remained substantively unchanged, and stated that “Tumor treatment field therapy (E0766) will be denied as not reasonable and necessary.” AR at 2506, 2577.

4. In 2018, Novocure requested that the DME MACs approve Medicare payment of TTFT for newly diagnosed GBM. AR at 2506. Novocure did not submit new evidence in support of revised coverage for recurrent GBM, which was not covered. *Id.*

5. Effective September 1, 2019, the LCD was revised to permit coverage for newly diagnosed GBM and continued coverage for newly diagnosed GBM beyond the first three months of therapy in certain circumstances. AR at 2501-02.

6. Novocure was “extremely pleased” with the 2019 LCD and notes that its coverage criteria “is generally similar to Optune’s commercial coverage criteria for newly diagnosed GBM.” *See* Medicare Releases Final Local Coverage Determination Providing Coverage of Optune® for Newly Diagnosed Glioblastoma, <https://www.novocure.com/medicare-releases-final-local-coverage-determination-providing-coverage-of-optune-for-newly-diagnosed-glioblastoma/> (last visited August 27, 2020).

7. On January 18, 2019, ALJ Glaze denied Plaintiff’s claim for Medicare coverage for treatment with the Optune system for her GBM from December 14, 2017 through February 14, 2018. AR at 2574.

8. After considering the arguments and evidence, ALJ Glaze found that Plaintiff’s GBM was not newly-diagnosed, but was rather recurrent. AR at 2576 (“the evidence does not sufficiently support that the Beneficiary’s glioblastoma is newly-diagnosed, but rather shows that she has been undergoing maintenance TTFT with MRI surveillance from 2013 through 2017 when, by October 4, 2017, there was radiographic evidence as compared to her two previous MRIs that there was likely recurrence and/or progression.”).

9. ALJ Glaze found that Plaintiff’s TTFT for her recurrent GBM was not supported. AR at 2576 (“TTFT continued to be used as maintenance therapy during the dates of service at issue without evidence of other treatment options

having been trialed, as suggested by the manufacturer and the [National Comprehensive Cancer Network].”).

10. ALJ Glaze concluded that the evidence Plaintiff offered was “insufficiently persuasive to overcome the substantial deference I must afford under 42 C.F.R. § 405.1162, to the existing Local Coverage Determination (LCD) L34823” AR at 2576.

11. ALJ Glaze noted that, on August 7, 2018, the Medical Directors of the Medicare Administrative Contractors issued a decision letter stating that “coverage language for newly-diagnosed glioblastoma would be altered, but that recurrent glioblastoma non-coverage language remains unchanged.” AR at 2576.

12. ALJ Glaze also noted that this administrative proceeding was not the proper venue for challenging the validity of the LCD. AR at 2577.

13. ALJ Glaze found that the record did not contain an Advance Beneficiary Notice and that Plaintiff’s liability for payment was waived. AR at 2577.

14. The ALJ decisions dated June 4, 2019, September 13, 2019, and January 29, 2020 were not in the record before ALJ Glaze. AR at 3169.

15. Plaintiff appealed ALJ Glaze’s unfavorable decision to the Medicare Appeals Council and subsequently requested to elevate her appeal to federal

district court. AR at 2446. Plaintiff filed the instant action instead of awaiting a decision by Council. *Id.*

16. On November 7, 2018, ALJ Gulin issued a favorable decision concerning Plaintiff's TTFT claims on September 14, 2017, October 14, 2017, and November 14, 2017. AR at 3186.

17. ALJ Gulin noted that he was not bound by the LCD, but must give it "substantial deference." AR at 3190. If an ALJ does not follow a LCD in "in a particular case, the [ALJ] must explain why in the decision." *Id.* (citing 42 C.F.R. § 405.1062).

18. ALJ Gulin found that Plaintiff's GBM was newly-diagnosed. AR at 3190.

19. ALJ Gulin declined to follow the LCD while also providing substantial deference to the LCD. AR at 3190.

20. ALJ Gulin concluded that: "[T]here is sufficient evidence supporting the Elec Stim Cancer Treatment (E0766) provided on the dates of service meets Medicare coverage criteria. The service was medically reasonable and necessary as required by Section 1862(a)(1)A) of the Act and the Appellant is entitled to Medicare coverage." AR at 3191.

Respectfully submitted,

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Dated: August 28, 2020

CERTIFICATE OF SERVICE

I hereby certify that on this day, I caused a true and correct copy of the foregoing Statement of Undisputed Material Facts to be served on all counsel of record via the Court's CM/ECF system.

/s/ Eric S. Wolfish
ERIC S. WOLFISH
Special Assistant United States Attorney

Dated: August 28, 2020